



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Fallaux et al.

Serial No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR
HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY

Confirmation No.: 5055

Examiner: D. Nguyen

Group Art Unit: 1632

Attorney Docket No.: 2578-3833.9US

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EL994843532US

Date of Deposit with USPS: August 4, 2005

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

08/09/2005 EFLORES 00000021 10618526

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Other Documents

WHITE et al., Adenovirus E1B 19-Kilodalton Protein Overcomes the Cytotoxicity of E1A Proteins, Journal of Virology, June 1991, pp. 2968-78, Vol. 65, No. 6.

WHITE et al., Role of Adenovirus E1B Proteins in Transformation: Altered Organization of Intermediate Filaments in Transformed Cells That Express the 19-Kilodalton Protein, Molecular and Cellular Biology, Jan. 1990, pp. 120-30, Vol. 10, No. 1.

GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome."

WHITE et al., Specific disruption of intermediate filaments and the nuclear lamina by the 19-kDa product of the adenovirus E1B oncogene, Proc. Natl. Acad. Sci., December 1989, pp. 9886-90, Vol. 86.

GALLIMORE et al., Transformation of Human Embryo Retinoblasts with Simian Virus 40, Adenovirus and ras Oncogenes, Anticancer Research, 1986, pp. 499-508, Vol. 6.

HITT et al., Construction and Propagation of Human Adenovirus Vectors, Cell Biology, 1994, pp. 479-90, Vol. 1, Academic Press, San Diego, California.

MITANI et al., Rescue, propagation, and partial purification of a helper virus-dependent adenovirus vector, Proc. Natl. Acad. Sci., April 1995, pp. 3854-58, Vol. 92.

MARCK, CHRISTIAN, 'DNA Strider': a 'C' program for the fast analysis of DNA and protein sequences on the Apple Macintosh family of computers, Nucleic Acids Research, 1988, pp. 1829-36, Vol. 16, No. 5.

PESHWA et al., Cultivation of Mammalian Cells as Aggregates in Bioreactors: Effect of Calcium Concentration on Spatial Distribution of Viability, 1993, pp. 179-87, Vol. 41.

BERG et al., High-Level Expression of Secreted Proteins from Cells Adapted to Serum-Free Suspension Culture, BioTechniques, 1993, pp. 972-78, Vol. 14, No. 6.

WHITE et al., The 19-Kilodalton Adenovirus E1B Transforming Protein Inhibits Programmed Cell Death and Prevents Cytolysis by Tumor Necrosis Factor alpha, Molecular and Cellular Biology, June 1992, pp. 2570-80, Vol. 12, No. 6.

COLBY et al., Adenovirus Type 5 Virions Can Be Assembled In Vivo in the Absence of Detectable Polypeptide IX, Journal of Virology, Sept. 1981, pp. 997-80, Vol. 39, No. 3.

RULEY, H. EARL, Adenovirus early region 1A enables viral and cellular transforming genes to transform primary cells in culture, Nature, August 1983, pp. 602-06, Vol. 304.

GRAHAM et al., Size and location of the transforming region in human adenovirus type 5 DNA, Nature, October 25, 1974, pp. 687-91, Vol. 251.

PRELICH et al., Functional Characterization of Thermolabile DNA-Binding Proteins That Affect Adenovirus DNA Replication, Journal of Virology, Mar. 1986, pp. 883-92, Vol. 57, No. 3.

WOODWORTH et al., Transformation of Differentiated Rat Hepatocytes with Adenovirus and Adenovirus DNA, Journal of Virology, Nov. 1987, pp. 3570-79, Vol. 61, No. 11.

RAO et al., The adenovirus E1A proteins induce apoptosis, which is inhibited by the E1B 19-kDa and Bcl-2 proteins, Proc. Natl. Acad. Sci., August 1992, pp. 7742-46, Vol. 89.

ROWE et al., Establishment and Characterization of Hamster Cell Lines Transformed by Restriction Endonuclease Fragments of Adenovirus 5, Journal of Virology, Jan. 1984, pp. 162-70, Vol. 49, No. 1.

SAMBROOK et al., Molecular Cloning -- A Laboratory Manual, 3rd edition, 2001, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York.

ACSADI et al., Adenovirus-mediated gene transfer into striated muscles, J Mol Med, 1995, pp. 165-80, Vol. 73.

NCBI database excerpt: Locus AC_000008 (human adenovirus type 5)

RHIM, JOHNG S., Development of Human Cell Lines from Multiple Organs, 2000, Annals New York Academy of Sciences, pp. 16-25.

Notice of Opposition to a European Patent by Serono International S.A. filed against Patent No. 0 833 934 (July 5, 2005).

Opposition lodged by Cevec Pharmaceuticals GmbH against European Patent 0 833 934 (July 5, 2005).

Although this Supplemental Information Disclosure Statement is filed after the issuance of a final office action, pursuant to 37 C.F.R. § 1.97(d), the undersigned submits that, to the best of his information and belief, "that each item of information contained in the [supplemental] information disclosure statement was first cited [a] communication (*i.e.*, transmittals of notices of opposition) from a foreign patent office (*i.e.*, the European Patent Office) in a counterpart foreign application not more than three months prior to the filing of the [supplemental] information disclosure statement". 37 C.F.R. § 1.97(e)(1). The fee set forth in 37 C.F.R. § 1.17(p) accompanies this Supplemental Information Disclosure Statement.

Respectfully submitted,



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Date: August 5, 2005

ACT/bv

Enclosures: Form PTO/SB/08
Copy of documents cited

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PTO/SB/08B(10-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/618,526
Sheet	1	Filing Date	July 11, 2003
	of 2	First Named Inventor	Fallaux et al.
		Group Art Unit	1632
		Examiner Name	D. Nguyen
		Attorney Docket Number	2578-3833.9US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
		WHITE et al., Adenovirus E1B 19-Kilodalton Protein Overcomes the Cytotoxicity of E1A Proteins, Journal of Virology, June 1991, pp. 2968-78, Vol. 65, No. 6.		
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

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		RULEY, H. EARL, Adenovirus early region 1A enables viral and cellular transforming genes to transform primary cells in culture, Nature, August 1983, pp. 602-06, Vol. 304.	
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